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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,589	11/07/2000	Christopher Perry	S-50035P1	9684

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/21/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,589

Applicant(s)

PERRY, CHRISTOPHER

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 23-25, 29-31, 35-41, 43, 44 and 46-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) 1-5, 16-19 and 25 is/are allowed.
- 6) ☒ Claim(s) 6-8, 14, 15, 23, 24, 29-31, 35-41, 43, 44 and 46-49 is/are rejected.
- 7) ☐ Claim(s) 9-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1638

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to claims 15, 16, 18, 37, 38, 41, and 45 are withdrawn in light of the claim amendments.
3. The rejections of claims 9-14, 16, 23, 24, 29, 30, and 38 under 35 U.S.C. 112, 2nd paragraph, are withdrawn in light of the claim amendments.

Claim Objections

4. Claims 9-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

5. Claim 6 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 18 September 2002 under item 9. Applicant traverses the in paper received 24 February 2003. Applicant's arguments have been fully considered but were not found persuasive.

Art Unit: 1638

Applicant argues that the concept of male sterility is well understood in the art, and that the claim provides clear warning to others as to what constitutes infringement of the claim (response, paragraph bridging pages 3-4). However, it is not clear how the plant became male sterile. Claim 6 depends from claim 2, which is drawn to the maize plant of inbred line NP2052. The specification does not define NP2052 as being male sterile. An indication of how the male sterility trait was added to NP2052 is necessary, as a male sterile plant is not within the scope of claim 2.

6. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite because it is dependent on cancelled claim 45.

7. Claims 7, 8, 14, 15, 23, 24, 29-31, 35-39, 43, 44, and 46-49 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 18 September 2002 under item 10. Applicant traverses the in paper received 24 February 2003. Applicant's arguments have been fully considered but were not found persuasive.

Art Unit: 1638

With regard to claims 7, 8, 14, 15, 43, and 45, Applicant argues that the word "trait" obtained from a gene or transgene as claimed, combined with the novel line NP2052, describes the subject matter of the claims. Applicant argues that one skilled in the breeding and biotechnological arts knows how to incorporate genes into different germplasm to produce desired traits, and that one does not need to know the corresponding phenotype or a gene or transgene to accomplish the incorporation (response, page 5, 1st full paragraph to the paragraph bridging pages 5-6). However, the word "trait" combined with NP2052 does not provide a description of the phenotype of the claimed plants. The specification describes the morphological and physiological traits of NP2052. However, a transgene or introgressed gene will change the combination of traits that describes NP2052. That those skilled in the art know how to incorporate genes into different germplasm is not the issue, as methods of making a product do not describe the product itself.

Regarding claims 23, 24, 29, 30, 35, 36, and 40, Applicant argues that the court in *Eli Lilly* specifically states that what is required under 35 U.S.C. 112, 1st paragraph is a description that distinguishes the claimed invention from other materials (response, page 6, 1st full paragraph). However, such a description has not been provided. Applicant argues that seed of NP2052 represents written description of the claimed subject matter of claims 1 and 2 as ruled in *Enzo Biochem v. Gen-Probe Incorporated* (response, page 6, 1st full paragraph). However, claims 1 and 2 have not been rejected. Applicant argues that those skilled in the art could distinguish any F1 hybrid made from NP2056 from any other hybrid, in that the presence of 1/2 of the genome of NP2056 in a hybrid line sufficiently distinguishes the genus of NP2056 derived hybrids from all other hybrids, and that no more is required under *Eli Lilly* (response, paragraph

Art Unit: 1638

bridging pages 6-7). However, the claimed hybrid will have $\frac{1}{2}$ of the genome of its other, unknown parent as well. The other parent is not described. Further, the mere presence of a trait in a plant that is also expressed by NP2056, is not an indication that NP2056 is a parent of that plant, as no individual trait expressed by NP2056 is unique to NP2056. The specification also does not describe any molecular markers or other identifying characteristics present in the NP2056 genome that would distinguish NP2056 genes from genes of all other corn lines.

Regarding method claims 31, 37-39, 44, 46-48, Applicant argues that 35 U.S.C. 112, first paragraph, only requires the claimed invention be described, and that these claims are directed to method steps which are described in detail. Applicant requests that if the Examiner is not persuaded, that support for "his position that unclaimed subject matter must be described" be provided (response, page 7, 1st full paragraph). It is not the Examiner's position that unclaimed subject be described. The claimed methods recite the use of products that must be described, in order for the claimed method to be described. As the as F1 plants and seeds, and plants having transgenes or introgressions are not described, and as such plants are required by the methods, the claimed methods are not described.

8. Claims 14, 40, and 41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 18 September 2002 under item 11. Applicant traverses

Art Unit: 1638

the in paper received 24 February 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that introgression of a single transgene trait into elite germplasm from source material has been a standard practice for many years. Applicant indicates that several publications were attached to the Reply that describe breeding methods to introgress transgenes into different genetic backgrounds (response, page 7, 3rd full paragraph to the paragraph bridging pages 7-8). However, no references were attached to Applicant's Reply.

Applicant argues addresses the Hunsperger reference, cited by the Examiner in last Office action. Applicants points out that the reference is directed to work in petunias, not corn (response, page 8, 1st full paragraph). However, Applicant does not point out why the findings are irrelevant to corn. Applicant also argues that introgression of the gene in Hunsperger was successful in the majority of genetic backgrounds (response, page 8, 1st full paragraph). However, introgression of the gene is not always successful provides an indication of the unpredictability of the process. Applicant submits that introgressing a single genetic trait into different genetic backgrounds is well within the skill of persons in the art, although admittedly it may require several generations of backcrossing and continual and careful selection of the desired phenotype (response, page 8 1st full paragraph). However, the claims also do encompass introgression involving single crosses.

Regarding Kraft et al., previously cited by the Examiner: Applicant argues that even if phenotypic variations occur because of linkage disequilibrium, the end plant product can still contain the selected single transgene expressing its gene product, and that the fact that the phenotype is slightly changed does not mean the process of transgene introgression is not

Art Unit: 1638

enabled (response, paragraph bridging pages 8-9). However, the specification does not teach any such "slightly changed" plants. The claimed plants only differ from NP2052 by the presence of the introgressed gene. The claimed method recites, "wherein the resulting maize line is inbred maize line NP2052 further comprising said single gene transferred trait". The claimed plants can only differ from NP2052 in the presence of the single transferred gene, and the specification does not teach any such plants.

Regarding Eshed et al., previously cited by the Examiner: Applicant argues that the experiments in the reference are based on introgressing large chromosome segments, not single transgenes (response, page 9, 1st full paragraph). However, Applicant does not explain why the conclusions drawn by Eshed et al. are irrelevant. Applicant directs attention to the first paragraph of the Discussion section, to a supposed statement by the author that QTL mapping studies have uncovered little evidence for epistasis (response, page 9, 1st full paragraph). First, the "statement" Applicant is referring to is only a portion of a sentence. That sentence goes on to indicate that using nearly isogenic lines, QTL epistasis is a significant component in determining phenotypic values. Applicants also point to a teaching on page 1813, first column, as indicating that genetic constitution of lines can be easily manipulated to generate shorter introgressions that retain the phenotypic effects (response, page 9, 1st full paragraph). However, Applicants have not taught that corn lines are as easily manipulated. The specification does not teach the production of any of the claimed lines comprising a single gene introgression in which the genome of NP2052 was also retained.

Art Unit: 1638

Summary

9. Claims 1-5, 16-19, and 25 are allowed. Claims 9-13 are objected to. Claims 6-8, 14, 15, 23, 24, 29-31, 35-41, 43, 44, and 46-49 remain rejected.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 703-306-3218. The fax phone numbers for the organization where

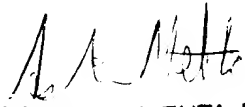
Application/Control Number: 09/707,589

Page 9

Art Unit: 1638

this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

May 12, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER.